



Printer's Error  
January 25, 2008

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## HOUSE BILL No. 1020

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DIGEST OF HB 1020 (Updated January 24, 2008 9:21 am - DI 77)

**Citations Affected:** IC 12-7; IC 12-31; IC 16-18; IC 16-21; noncode.

**Synopsis:** Umbilical cord blood bank. Requires the office of the secretary of family and social services to form a nonprofit corporation to establish and operate an umbilical cord blood bank. Requires suitable postnatal donations to be available for medical treatments and scientific research. Requires the nonprofit corporation to develop a process for physicians, nurse midwives, and participating hospitals to inform pregnant patients of the option to make postnatal donations following delivery of a newborn infant. Requires the nonprofit corporation to establish an umbilical cord blood donation initiative to promote public awareness concerning the medical benefits of umbilical cord blood. (The introduced version of this bill was prepared by the health finance commission.)

**Effective:** July 1, 2008.

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**Welch, Koch, Battles, Turner**

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January 14, 2008, read first time and referred to Committee on Public Health.  
January 24, 2008, amended, reported — Do Pass.

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HB 1020—LS 6119/DI 104+



Second Regular Session 115th General Assembly (2008)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2007 Regular Session of the General Assembly.

## HOUSE BILL No. 1020

A BILL FOR AN ACT to amend the Indiana Code concerning health.

*Be it enacted by the General Assembly of the State of Indiana:*

- 1 SECTION 1. IC 12-7-2-118.3 IS ADDED TO THE INDIANA
- 2 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 3 [EFFECTIVE JULY 1, 2008]: **Sec. 118.3. "Initiative", for purposes**
- 4 **of IC 12-31-2, has the meaning set forth in IC 12-31-2-1.**
- 5 SECTION 2. IC 12-7-2-132.5 IS ADDED TO THE INDIANA
- 6 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 7 [EFFECTIVE JULY 1, 2008]: **Sec. 132.5. "Nonprofit corporation",**
- 8 **for purposes of IC 12-31, has the meaning set forth in IC 12-31-1-1.**
- 9 SECTION 3. IC 12-7-2-142.7 IS ADDED TO THE INDIANA
- 10 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 11 [EFFECTIVE JULY 1, 2008]: **Sec. 142.7. "Postnatal donation", for**
- 12 **purposes of IC 12-31, has the meaning set forth in IC 12-31-1-2.**
- 13 SECTION 4. IC 12-31 IS ADDED TO THE INDIANA CODE AS
- 14 A **NEW** ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1,
- 15 2008]:
- 16 **ARTICLE 31. UMBILICAL CORD BLOOD**
- 17 **Chapter 1. Public Umbilical Cord Blood Bank**

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1        **Sec. 1.** As used in this article, "nonprofit corporation" refers to  
 2        the Indiana nonprofit corporation that is formed by the office of  
 3        the secretary under section 2 of this chapter to establish and  
 4        operate a public umbilical cord blood bank.

5        **Sec. 2.** As used in this article, "postnatal donation" means any  
 6        of the following donations by a patient to the public umbilical cord  
 7        blood bank:

8            (1) Postnatal fluid, including umbilical cord blood.

9            (2) Postnatal tissue, including the placenta and tissue  
 10          extracted from an umbilical cord.

11        **Sec. 3.** (a) The office of the secretary shall form a nonprofit  
 12        corporation to establish and provide for the operation of a public  
 13        umbilical cord blood bank to promote public health and to exercise  
 14        other essential governmental functions.

15        (b) The office of the secretary shall adopt rules under IC 4-22-2  
 16        concerning the protection of individual identifiable health  
 17        information regarding the operation of the public umbilical cord  
 18        blood bank.

19        **Sec. 4.** (a) The board of directors of the nonprofit corporation  
 20        consists of the following:

21            (1) The state health commissioner or the commissioner's  
 22            designee.

23            (2) The secretary or the secretary's designee.

24            (3) The secretary of commerce appointed under IC 5-28-3-4  
 25            or the secretary's designee.

26            (4) The director of the state department of health's office of  
 27            minority health.

28            (5) The following individuals appointed by the governor:

29                (A) One (1) president or chief executive officer of an  
 30                Indiana based hospital.

31                (B) One (1) research scientist with expertise in umbilical  
 32                cord blood research.

33                (C) One (1) ethicist with expertise in bioethics.

34                (D) One (1) physician licensed under IC 25-22.5 who  
 35                specializes in birthing and delivery.

36                (E) One (1) representative of a donor cord blood bank  
 37                facility.

38                (F) One (1) member of the interagency state council on  
 39                black and minority health established under IC 16-46-6.

40        (b) The board of directors shall appoint an advisory board. At  
 41        least fifty-one percent (51%) of the advisory board members must  
 42        be research scientists with expertise in stem cell research.

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(c) The advisory board, using criteria established by the board of directors, is responsible for reviewing applications from research scientists, research institutions, and other persons interested in receiving a postnatal donation that is ineligible for transplant use from the public umbilical cord blood bank.

(d) The board of directors may contract with a person to perform the management and administrative operations of the public umbilical cord blood bank. The person shall follow the federal Food and Drug Administration's current good tissue practices.

(e) Subject to approval by the budget agency, the board of directors may, without the approval of the attorney general, employ legal counsel, technical experts, and other officers, agents, and employees that the board of directors considers necessary to carry out the efficient operation of a public umbilical cord blood bank.

(f) The board of directors shall determine the terms and conditions of the participating agreement that is executed with each participating hospital.

**Sec. 5. The nonprofit corporation shall do the following:**

- (1) Establish procedures and guidelines for collecting, maintaining, and receiving postnatal donations.
- (2) Educate health care professionals about the procedures and requirements for collecting and maintaining postnatal donations following the birth of a newborn infant.
- (3) Establish procedures concerning patient informed consent and privacy that are approved by an independent institutional review board selected by the board of directors.

**Sec. 6. (a) The nonprofit corporation shall accept and maintain postnatal donations at no charge or cost to the donor.**

**(b) The nonprofit corporation may allow the following to use the postnatal donations:**

- (1) Transplant centers.
- (2) Research centers approved by the nonprofit corporation that will use the postnatal donation to promote medical advances, life science research, or biotechnology research.
- (3) Any other entity approved by the nonprofit corporation if the entity will use the postnatal donation to promote medical advances, life science research, or biotechnology research.

**(c) All postnatal donations donated that are of transplantable quality as set forth by the National Marrow Donor Program or other federal Food and Drug Administration approved protocol**

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1 must be allocated for medical transplants.

2 (d) Postnatal donations that are donated to the public umbilical  
3 cord blood bank that do not meet the transplant requirements may  
4 be allocated by the bank for research purposes.

5 (e) The nonprofit corporation shall acquire and maintain  
6 adequate liability insurance coverage.

7 Sec. 7. (a) The nonprofit corporation may collect and maintain  
8 the postnatal donations at no charge or cost to the donor.

9 (b) Any postnatal donations maintained by the public umbilical  
10 cord blood bank that are of transplantable quality or suitable for  
11 research must be made available for scientific research or medical  
12 treatments that comply with relevant national practice and quality  
13 standards.

14 Sec. 8. The nonprofit corporation may award a grant to a  
15 person for work with postnatal donations.

16 Sec. 9. The nonprofit organization shall report annually to the  
17 health finance commission established by IC 2-5-23-3 concerning  
18 the following:

19 (1) The implementation of the umbilical cord blood bank.

20 (2) The number of postnatal donations used for transplants  
21 and the number of postnatal donations used for research.

## 22 Chapter 2. Umbilical Cord Blood Donation Initiative

23 Sec. 1. As used in this chapter, "initiative" refers to the  
24 umbilical cord blood donation initiative established under section  
25 2 of this chapter.

26 Sec. 2. The nonprofit corporation shall establish an umbilical  
27 cord blood donation initiative to promote public awareness  
28 concerning the following:

29 (1) A pregnant woman's option to make a postnatal donation  
30 upon the birth of a newborn infant.

31 (2) The medical benefits of postnatal tissue and postnatal  
32 fluids.

33 (3) The importance of donating umbilical cord blood to the  
34 public umbilical cord blood bank.

35 Sec. 3. The nonprofit corporation may accept a grant from the  
36 federal government or money from the state government or private  
37 contributions to establish and implement the initiative.

38 Sec. 4. (a) The initiative must include the dissemination of  
39 written material that includes the following:

40 (1) Information concerning the option that is available to  
41 pregnant women to make a postnatal donation upon the birth  
42 of a newborn infant.

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(2) An explanation of the benefits of public umbilical cord blood banking.

(3) The benefits of umbilical cord blood in accordance with the National Marrow Donor Program or other federal Food and Drug Administration approved protocol and the use of umbilical cord blood for medical treatment, including the following:

(A) A list of the diseases or conditions that have been treated through the use of umbilical cord blood.

(B) A list of the diseases or conditions for which scientific research indicates that treatment through the use of umbilical cord blood is promising.

(4) Information on the public umbilical cord blood bank.

(5) Information concerning the process by which postnatal tissue and postnatal fluid is collected and the steps that a pregnant woman must take before the child is born to arrange to have the postnatal tissue and postnatal fluid collected and donated.

(b) The nonprofit corporation shall:

(1) update the material required in subsection (a); and

(2) distribute the material to the following persons that treat pregnant women:

(A) Physicians licensed under IC 25-22.5.

(B) Participating hospitals.

(C) Ambulatory surgical centers.

(D) Health clinics.

(E) Maternity homes registered under IC 16-26-1.

(F) Nurse midwives licensed under IC 25-23-1-13.1.

**Sec. 5.** The nonprofit corporation shall develop a process for physicians, nurse midwives, and participating hospitals to inform eligible candidates of the opportunity to make postnatal donations to the public umbilical cord blood bank following delivery of a newborn infant.

**Sec. 6.** The nonprofit corporation that establishes the initiative described in this chapter must meet all the requirements and responsibilities set forth in IC 23-17.

**Sec. 7.** (a) Any intellectual property developed by the nonprofit corporation establishing the initiative under this chapter is the property of the nonprofit corporation. A donor must consent to release to the public umbilical cord blood bank any property right related to the postnatal donation, including any claim of intellectual property rights derived from the postnatal donation.

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(b) The entire right, title, and interest in and to any intellectual property derived from a postnatal donation transfers with the postnatal tissue and postnatal fluid after the postnatal donation is allocated by the public umbilical cord blood bank for research purposes.

SECTION 5. IC 16-18-2-36.5, AS ADDED BY P.L.96-2005, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 36.5. (a) "Birthing center", for purposes of IC 16-21-2 and IC 16-21-7.5, means a freestanding entity that has the sole purpose of delivering a normal or uncomplicated pregnancy.

(b) The term does not include a hospital that is licensed as a hospital under IC 16-21-2.

SECTION 6. IC 16-21-7.5 IS ADDED TO THE INDIANA CODE AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]:

**Chapter 7.5. Hospital and Birthing Center Requirement Regarding Umbilical Cord Blood Donation**

**Sec. 1.** As used in this chapter, "postnatal donation" has the meaning set forth in IC 12-31-1-2.

**Sec. 2.** Before a hospital or birthing center participates in collecting donations for the public umbilical cord blood bank, the hospital or birthing center shall enter into a written agreement with the public umbilical cord blood bank establishing the:

- (1) conditions of the hospital's or birthing center's participation; and
- (2) obligations of the hospital or birthing center; in the umbilical cord donation initiative.

**Sec. 3.** (a) Except as provided in section 4 of this chapter, a participating hospital or birthing center licensed under this article must offer a patient who delivers a newborn infant at the participating hospital or birthing center the option of making a postnatal donation following delivery of the newborn infant.

(b) A patient may not be charged for the collection, storage, or donation to the public umbilical cord blood bank established under IC 12-31-1.

**Sec. 4.** (a) A participating hospital or birthing center is not required to collect the postnatal donation if either of the following applies:

- (1) In the professional judgment of a physician licensed under IC 25-22.5 or a nurse midwife licensed under IC 25-23-1-13.1, the collection would threaten the health of the mother or the infant.

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1           (2) The participating hospital or birthing center is affiliated  
2           with a religious denomination that believes that the blood  
3           transfer is contrary to the moral principles or beliefs of the  
4           religious denomination.

5           (b) An employee of a participating hospital or birthing center is  
6           not required to collect a postnatal donation if the blood transfer is  
7           contrary to the religious principles or beliefs of the employee.

8           Sec. 5. A participating hospital or birthing center shall  
9           cooperate with the nonprofit corporation (as defined in  
10          IC 12-31-1-1) in accomplishing the public health goal of  
11          maximizing postnatal donations.

12          Sec. 6. A hospital or birthing center is not required to enter into  
13          an agreement with the public umbilical cord blood bank and may  
14          enter into contracts concerning postnatal tissue and postnatal  
15          fluids with any person.

16          SECTION 7. [EFFECTIVE JULY 1, 2008] (a) The office of the  
17          secretary of family and social services shall immediately begin the  
18          adoption of the rules required under IC 12-31-1-3, as added by this  
19          act, and adopt the final rules before March 1, 2009.

20          (b) This SECTION expires July 1, 2009.

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## COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1020, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 1, between lines 8 and 9, begin a new paragraph and insert the following:

"SECTION 3. IC 12-7-2-142.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: **Sec. 142.7. "Postnatal donation", for purposes of IC 12-31, has the meaning set forth in IC 12-31-1-2.**"

Page 1, line 15, delete "enters into a memorandum" and insert "**is formed by**".

Page 1, line 16, delete "of understanding with".

Page 2, between lines 1 and 2, begin a new paragraph and insert:

**"Sec. 2. As used in this article, "postnatal donation" means any of the following donations by a patient to the public umbilical cord blood bank:**

**(1) Postnatal fluid, including umbilical cord blood.**

**(2) Postnatal tissue, including the placenta and tissue extracted from an umbilical cord."**

Page 2, line 2, delete "2." insert "**3. (a)**".

Page 2, line 2, delete "enter into a" and insert "**form**".

Page 2, line 3, delete "memorandum of understanding with".

Page 2, between line 6 and 7, begin a new paragraph and insert the following:

**"(b) The office of the secretary shall adopt rules under IC 4-22-2 concerning the protection of individual identifiable health information regarding the operation of the public umbilical cord blood bank."**

Page 2, line 7, delete "3." and insert "**4.**".

Page 2, line 34, delete "purchasing umbilical cord blood or a placenta" and insert "**receiving a postnatal donation**".

Page 2, line 39, after "bank." insert "**The person shall follow the federal Food and Drug Administration's current good tissue practices.**".

Page 2, between lines 39 and 40, begin a new paragraph and insert:

**"(e) Subject to approval by the budget agency, the board of directors may, without the approval of the attorney general, employ legal counsel, technical experts, and other officers, agents, and employees that the board of directors considers necessary to carry out the efficient operation of a public umbilical cord blood**

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bank.

(f) The board of directors shall determine the terms and conditions of the participating agreement that is executed with each participating hospital."

Page 2, line 40, delete "4." and insert "5."

Page 2, line 41, delete "and" and insert ",".

Page 2, line 42, delete "umbilical cord blood" and insert ", and receiving postnatal".

Page 3, line 2, delete "umbilical" and insert " postnatal".

Page 3, line 3, delete "cord blood".

Page 3, line 4, delete "forms" and insert "procedures".

Page 3, line 5, delete "." and insert "that are approved by an independent institutional review board selected by the board of directors."

Page 3, line 6, delete "5." and insert "6."

Page 3, line 7, delete "umbilical cord blood" and insert "postnatal".

Page 3, line 9, delete "umbilical cord blood" and insert "postnatal".

Page 3, line 12, delete "umbilical cord blood" and insert "postnatal".

Page 3, line 16, delete "umbilical cord blood" and insert "postnatal".

Page 3, line 19, delete "umbilical cord blood donations to the public umbilical" and insert "postnatal donations donated that are".

Page 3, line 20, delete "cord blood bank".

Page 3, line 21, after "Program" add "or other federal Food and Drug Administration approved protocol".

Page 3, line 23, delete "Umbilical cord blood donations" and insert "Postnatal donations that are donated".

Page 3, between lines 25 and 26, begin a new paragraph and insert: "(e) The nonprofit corporation shall acquire and maintain adequate liability insurance coverage."

Page 3, line 26, delete "6." and insert "7."

Page 3, line 27, delete "donations of tissue extracted from an umbilical cord and placenta" and insert "the postnatal donations".

Page 3, line 29, delete "tissue" and insert "donations".

Page 3, line 30, after "bank" insert "that are of transplantable quality or suitable for research".

Page 3, line 33, delete "7." and insert "8."

Page 3, line 34, delete "umbilical cord blood or postnatal tissue." and insert "postnatal donations."

Page 3, line 35, delete "8." and insert "9."

Page 3, line 39, delete "collections" and insert "postnatal

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**donations".**

Page 3, line 40, delete "collections" and insert **"postnatal donations".**

Page 4, line 6, delete "donate umbilical cord blood." and insert **"make a postnatal donation."**

Page 4, line 8, delete "umbilical cord blood." and insert **"postnatal tissue and postnatal fluids."**

Page 4, line 17, delete "donate umbilical cord blood" and insert **"make a postnatal donation".**

Page 4, lines 19, delete "the difference between public and" and insert **"the benefits of public".**

Page 4, line 20, delete "private".

Page 4, line 22, after "Program" add **"or other federal Food and Drug Administration approved protocol".**

Page 4, line 30, delete "umbilical" and insert **"postnatal tissue and postnatal fluid".**

Page 4, line 31, delete "cord blood".

Page 4, line 33, delete "umbilical cord blood" and insert **"postnatal tissue and postnatal fluid".**

Page 4, line 39, delete "Hospitals." and insert **"Participating hospitals."**

Page 4, after line 42, begin a new line double block indented and insert:

**"(F) Nurse midwives licensed under IC 25-23-1-13.1."**

Page 5, delete lines 1 through 6, begin a new paragraph and insert:

**"Sec. 5. The nonprofit corporation shall develop a process for physicians, nurse midwives, and participating hospitals to inform eligible candidates of the opportunity to make postnatal donations to the public umbilical cord blood bank following delivery of a newborn infant."**

Page 5, line 13, delete "any claim of intellectual property derived from an" and insert **"to the public umbilical cord blood bank any property right related to the postnatal donation, including any claim of intellectual property rights derived from the postnatal donation."**

Page 5, delete lines 14 through 18, begin a new paragraph and insert:

**"(b) The entire right, title, and interest in and to any intellectual property derived from a postnatal donation transfers with the postnatal tissue and postnatal fluid after the postnatal donation is allocated by the public umbilical cord blood bank for research purposes."**



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SECTION 4. IC 16-18-2-36.5, AS ADDED BY P.L.96-2005, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2008]: Sec. 36.5. (a) "Birthing center", for purposes of IC 16-21-2 **and IC 16-21-7.5**, means a freestanding entity that has the sole purpose of delivering a normal or uncomplicated pregnancy.

(b) The term does not include a hospital that is licensed as a hospital under IC 16-21-2."

Page 5, line 22, after "Hospital" insert **"and Birthing Center"**.

Page 5, between lines 23 and 24, begin a new paragraph and insert:

**"Sec. 1. As used in this chapter, "postnatal donation" has the meaning set forth in IC 12-31-1-2.**

**Sec. 2. Before a hospital or birthing center participates in collecting donations for the public umbilical cord blood bank, the hospital or birthing center shall enter into a written agreement with the public umbilical cord blood bank establishing the:**

**(1) conditions of the hospital's or birthing center's participation; and**

**(2) obligations of the hospital or birthing center; in the umbilical cord donation initiative."**

Page 5, line 24, delete "1." and insert **"3."**

Page 5, line 24, delete "2" and insert **"4"**.

Page 5, line 25, after "hospital" insert **"or birthing center"**.

Page 5, line 26, after "hospital" insert **"or birthing center"**.

Page 5, line 27, delete "donating the umbilical cord blood" and insert **"making a postnatal donation"**.

Page 5, line 32, delete "2." and insert **"4."**

Page 5, line 32, before "hospital" insert **"participating"**.

Page 5, line 32, after "hospital" insert **"or birthing center"**.

Page 5, line 32, delete "umbilical cord" and insert **"postnatal donation"**.

Page 5, line 33, delete "blood".

Page 5, line 35, delete "," and insert **"or a nurse midwife licensed under IC 25-23-1-13.1,"**.

Page 5, line 37, before "hospital" insert **"participating"**.

Page 5, line 37, after "hospital" insert **"or birthing center"**.

Page 5, line 40, after "hospital" insert **"or birthing center"**.

Page 5, line 41, delete "an umbilical cord blood" and insert **"a postnatal"**.

Page 6, line 1, delete "3." and insert **"5."**

Page 6, line 1, before "hospital" insert **"participating"**.

Page 6, line 1, after "hospital" insert **"or birthing center"**.

Page 6, line 3, delete "umbilical cord blood" insert **"postnatal"**.

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Page 6, after line 3, begin a new paragraph and insert:

**"Sec. 6. A hospital or birthing center is not required to enter into an agreement with the public umbilical cord blood bank and may enter into contracts concerning postnatal tissue and postnatal fluids with any person.**

**SECTION 5. [EFFECTIVE JULY 1, 2008] (a) The office of the secretary of family and social services shall immediately begin the adoption of the rules required under IC 12-31-1-3, as added by this act, and adopt the final rules before March 1, 2009.**

**(b) This SECTION expires July 1, 2009."**

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1020 as introduced.)

BROWN C, Chair

Committee Vote: yeas 10, nays 0.

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